UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/587,855 | 07/28/2006 | Werner Mederski | MERCK-3199 | 9832 |
| 23599 7590 01/27/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. | | | EXAMINER | |
| | | | SHAMEEM, GOLAM M | |
| SUITE 1400 ARLINGTON, VA 22201 | | | ART UNIT | PAPER NUMBER |
| | | | 1626 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 01/27/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) |
|---|--|---|
| | 10/587,855 | MEDERSKI ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | Golam M. M. Shameem | 1626 |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | orrespondence address |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from a, cause the application to become ABANDONE | Lely filed the mailing date of this communication. O (35 U.S.C. § 133). |
| Status | | |
| Responsive to communication(s) filed on <u>28 Jules</u> This action is FINAL . 2b) ☐ This action is application is in condition for allowed closed in accordance with the practice under Expression in the Expression in | action is non-final. nce except for formal matters, pro | |
| Disposition of Claims | | |
| 4) Claim(s) 1-19 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-19 are subject to restriction and/or of | wn from consideration. | |
| Application Papers | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11. | epted or b) objected to by the Ediaming of the Idrawing of the held in abeyance. See tion is required if the drawing of is obj | ected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Application rity documents have been receive u (PCT Rule 17.2(a)). | on No ed in this National Stage |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | te |

Application/Control Number: 10/587,855 Page 2

Art Unit: 1626

DETAILED ACTION

Claims 1-19 are currently pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Restriction is based on PCT Rule 13.1, 13.2 and Annex B part 1(b) together with 37 CFR 1.475 and 1.499 for lacking unity of invention because of lacking a significant structural element qualifying as the special technical features.

Claims 1-19 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that "special technical features" mean those technical features, which as a whole define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claim for a process specially

Application/Control Number: 10/587,855 Page 3

Art Unit: 1626

adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-9 drawn to a compound of formula I classified in classes 544, 546 and numerous subclasses.
- II. Claim 10 drawn to a process for preparing a compound of formula I classified in classes 544, 546 and several subclasses.
- III. Claims 11 and 12 drawn to a method of use of a compound classified in class 514 and several subclasses.
- IV Claims 13 and 14 drawn to a method of use of a compound classified in class 514 and several subclasses.
- V Claims 15 and 17 drawn to another method of use of a compound classified in class 514 and several subclasses.
- VI Claim 16 drawn to a Set (kit) classified in class 514 and several subclasses.
- VII Claims 18 and 19 drawn to intermediate compound of formula II-1 classified in classes 544, 546 and several subclasses.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features that define a contribution over the prior art. The invention Groups I-VII outlined above each relate to a set of structurally diverse and dissimilar compounds, process for preparing and their method of uses which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious. Accordingly, the unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Page 4

This application contains claims directed to more than one compound of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicant is required, in reply to this action, to elect a single species (compound) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants preserve their right to file a divisional on the non-elected subject matter.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, whose telephone number is (571) 272-0706. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (571) 273-8300. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of

Application/Control Number: 10/587,855 Page 6

Art Unit: 1626

record in the application file. PTO employees will not communicate with applicant via Internet

e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive

data could be identified unless there is of record an express waiver of the confidentiality

requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG

89.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or public PAIR only. For more information about the

pair system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197.

Any inquiry of a general nature or relating to the status of this application should be

directed to the Group receptionist, whose telephone number is (571) 272-1600.

/Golam M. M. Shameem/

Primary Examiner

Art Unit 1626

Technology Center 1600

Application/Control Number: 10/587,855

Page 7

Art Unit: 1626